

SPECIAL 510(k): Device Modification OIR Decision Summary

To: Becton Dickinson and Company

RE: K152870

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.
BD Veritor™ System for Rapid Detection of Flu A+B (CLIA waived kit)
K112277, K132259, K132692, K151291
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
This device modification was for the addition of 6 different influenza virus strains to the reactivity table provided in the package insert. The viruses added are 1 influenza A/H3N2 virus and 5 influenza B viruses: 3 Victoria Lineage and 2 Yamagata Lineage. The table below shows the strains used in testing and the estimated Limit of Detection (LoD) using the device.

No.	Strain	Final Dilution Factor	Estimated LOD
1	A/California/02/2014 (H3N2)	4000	1.45×10^2 TCID50/mL
2	B/Brisbane/33/2008 (Victoria Lineage)	200	2.45×10^5 CEID50/mL
3	B/Guangdong-Liwan/1133/2014 (Yamagata Lineage)	2000	9.0×10^5 CEID50/mL
4	B/Hong Kong/259/2010 (Victoria Lineage)	400	1.35×10^6 CEID50/mL
5	B/Texas/02/2013 (Victoria Lineage)	4000	2.75×10^4 CEID50/mL
6	B/Utah/09/2014 (Yamagata Lineage)	10000	6.3×10^3 CEID50/mL

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and specimen type and analytical reactivity.

Similarities:		
Product Feature	Currently Marketed Veritor™ System Flu A + B kit (k 151291)	Product Modification
Intended use	<p>The BD Veritor System for Rapid Detection of Flu A+B is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasal and nasopharyngeal swabs of symptomatic patients. The BD Veritor System for Rapid Detection of Flu A+B (also referred to as the BD Veritor System and BD Veritor System Flu A+B) is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. A negative test is presumptive and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Outside the U.S., a negative test is presumptive and it is recommended that these results be confirmed by viral culture or a molecular assay cleared for diagnostic use in the country of use. FDA has not cleared this device for use outside of the U.S. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. The test is not intended to detect influenza C antigens. Performance characteristics for influenza A and B were established during January through March of 2011 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the <i>Morbidity and Mortality Weekly Report</i> from the CDC entitled "Update: Influenza Activity—United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses.</p> <p>If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel</p>	unchanged

	virulent influenza viruses and sent to the state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.	
Specimen type	Nasopharyngeal swabs in transport media and nasopharyngeal wash aspirates	unchanged
Assay technology	Immunochromatographic	unchanged
Detection Format	An opto-electronic reader determines the line intensity at each of the spatially defined test and control line positions, interprets the results using a scoring algorithm and reports a positive, negative or invalid result on the LCD screen based on pre-set thresholds.	unchanged
Qualitative or Quantitative	Qualitative	unchanged
Assay run time	approximately 10 minutes	unchanged
Control format	<ul style="list-style-type: none"> • Kit Flu A+/B- dry swab procedural control • Kit Flu A-/B+ dry swab procedural control • Internal positive control • Internal negative control 	unchanged
Detection of Flu A and B viruses	differentiation A vs. B	unchanged
Differences:		
Analytical Strain Reactivity Tables in Labeling (Package Insert)	Current Product Package Insert includes 73 Flu Strains; 36 Flu A and 37 Flu B in the Analytical Strain reactivity tables.	Analytical Strain reactivity tables in the Package Insert contain reactivity data regarding 6 additional Influenza strains

5. A **Design Control Activities Summary** which includes:
- a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.

The Risk Analysis method used was based on a BD Product Risk Management procedure which meets the requirement for risk management as set forth in ISO14971:2007 and EN ISO 14971:2012.

Hazard	False Negative		Risk Control Measure	Testing
Adverse Effect (Harm)	Effect on patient is that they could be inappropriately treated leading to flu progression			Obtain and test additional flu strains
Probability of Severity	S-3			Labeling
Potential Causes of the Hazard	Assay does not detect the predicted strains for 2015/2016 Flu Season or other available new and circulating strains			Update PI with new reactivity after FDA special 510(k) clearance
Probability of Occurrence	P-3		Risk Control Measure Effectiveness	SDSP15001
Existing Risk Control Measure	Current strain reactivity has been determined and is provided in the Product Insert		Probability of Severity	S-3
Risk Index	YE		Probability of Occurrence	P-1
Responsibility for Risk Control Measure	R&D		Risk Index	GR

- b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.

The results of the analysis indicated an initial possible combination of severity and occurrence that fell into S-3/P-3 category. To implement the indicated investigation, a protocol was developed and approved based on previously accepted FDA submissions regarding strain reactivity. Acceptability criteria were defined as the ability of the BD Veritor™ test to detect the additional Flu strains. The results of the strain testing reduced the probability of occurrence from P-3 to P-1 and reduced the risk to the “negligible” category.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.